TECHNICAL MANUAL

CADD-Prizm® PCSII
AMBULATORY INFUSION PUMP

MODEL 6101

Deltec

For detailed instructions, specifications, warnings, warranties and additional information on operating CADD® pumps, please refer to the *Operator's Manual* supplied with the product. If you have additional comments or questions concerning the operation of CADD® pumps, please call this number: **(800) 426-2448**. Our staff is available to help you 24 hours a day with the programming and operation of CADD® pump infusion systems.

The issue date of this Technical Manual is included for the user's information. In the event one year has elapsed between the issue date and product use, the user should contact Deltec, Inc. to see if a later revision of this manual is available.

Issue Date: July 2003

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1 Introduction

The Technical Manual is intended to provide a basic, but limited, understanding of the mechanical and electrical operation of the Deltec CADD-Prizm® PCS II Computerized Ambulatory Drug Delivery pump to persons familiar with this device. The CADD-Prizm® PCS II *Operator's Manual* should be used in conjunction with this publication for complete information.

This manual also outlines cleaning and functional testing procedures that can be performed on the CADD-Prizm® PCS II pump.

This technical manual is applicable to the CADD-Prizm® PCS II pump only.

IMPORTANT NOTICE:

CADD-Prizm® PCS II pump operations and safety features are based on a microcomputer design. Inadequate servicing or tampering with the safety features of the pump may seriously affect performance and safety.

For that reason, **ALL SERVICING AND REPAIR OF THE CADD-Prizm® PCS II PUMP MUST BE PERFORMED BY DELTEC OR ITS AUTHORIZED AGENTS.**

The manufacturer's warranty agreement shall become null and void if the pump is not used in accordance with the *Operator's Manual* and *Instructions for Use* for the pump accessories; or, the pump is serviced by persons other than Deltec or those authorized by Deltec.

Limited Warranty

The limited warranty associated with the CADD-Prizm® PCS II pump can be found in the product literature supplied with the product when originally purchased, which is incorporated herein by reference. DELTEC SPECIFICALLY DISCLAIMS ANY OTHER WARRANTY, WHETHER EXPRESS, IMPLIED OR STATUTORY, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR USE. Deltec further disclaims responsibility for the suitability of the system for a particular medical treatment or for any medical complications resulting from the use of the system.

The manufacturer shall not be responsible for any incidental damages or consequential damages to property, loss of profits, or loss of use caused by any defect or malfunction of the system.

If you wish to receive additional information about the extent of the warranty on these products, please contact your Deltec representative or call Customer Service at (800) 426-2448.

All recommendations, information and literature supplied by Deltec with respect to the CADD® product line are believed to be accurate and reliable, but do not constitute warranties. No agent, representative, or employee of Deltec has authority to bind Deltec to any representation or warranty, expressed or implied.

Exposure to Radiation or Magnetic Resonance Imaging (MRI)

CAUTIONS:

(1) The pump SHOULD NOT BE DIRECTLY IRRADIATED by therapeutic levels of ionizing radiation because of the risk of permanent damage to the pump's electronic circuitry. The best procedure to follow is to remove the pump from the patient during therapeutic radiation sessions or diagnostic levels of radiographic and fluoroscopic radiation. If the pump must remain in the vicinity during a diagnostic or therapy session, it should be shielded, and its ability to function properly should be confirmed following treatment.

(2) Magnetic fields produced by magnetic resonance imaging (MRI) equipment may adversely affect the operation of the pump. Remove the pump from the patient during MRI procedures and keep it at a safe distance from magnetic energy.

2 CADD-Prizm® Pump

Delivery Modes

The Deltec CADD-Prizm® PCS II pump provides measured drug therapy to patients. CADD-Prizm® PCS II pumps are indicated for intravenous, intra-arterial, subcutaneous, intraperitoneal, epidural space or subarachnoid space infusion. Epidural administration is limited to short-term infusion of anesthetics and either long- or short-term infusion of analgesics. Subarachnoid administration is limited to short-term infusion of analgesics.

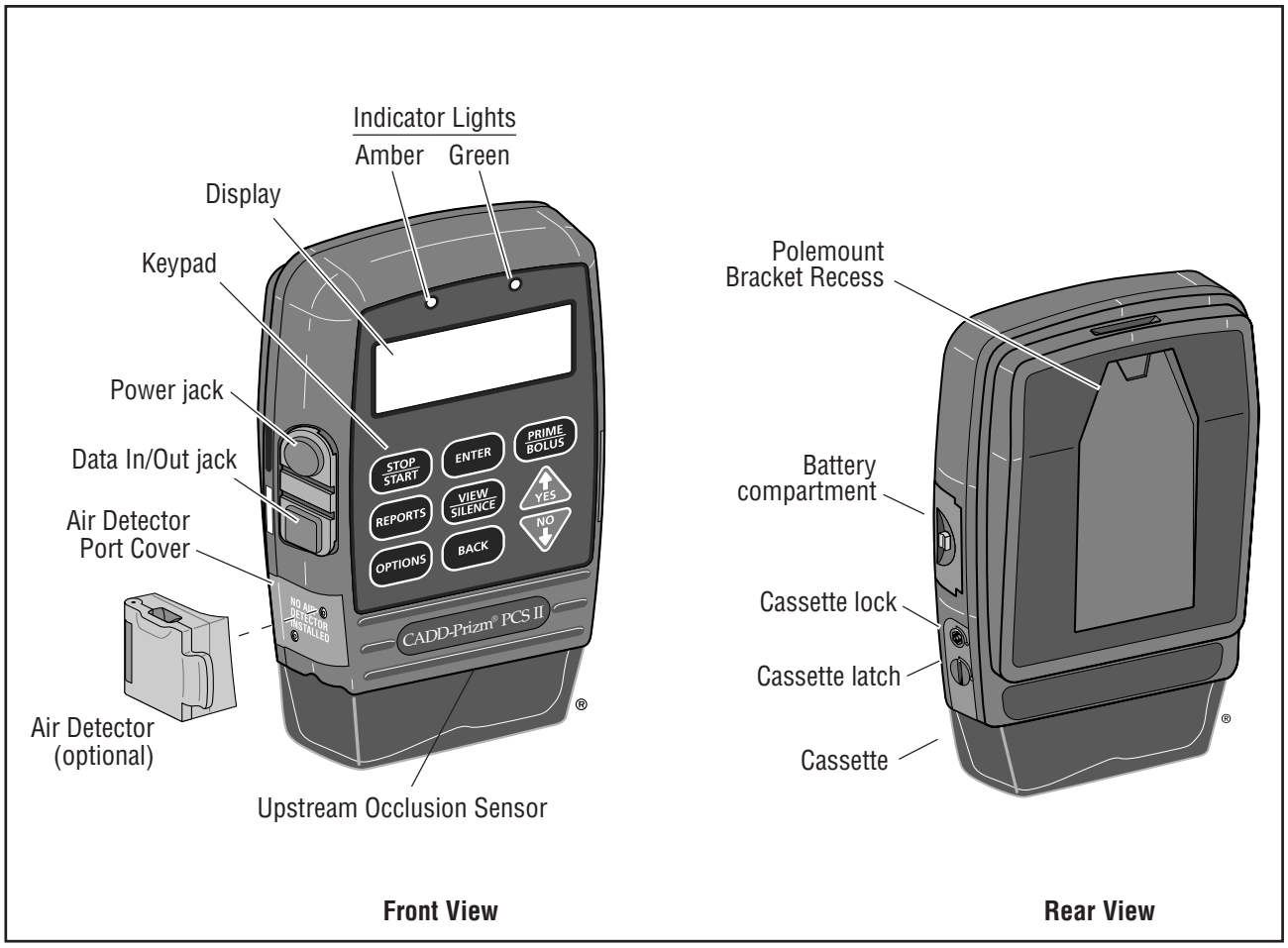


Figure 1. Front and back views of the CADD-Prizm® PCS II pump.

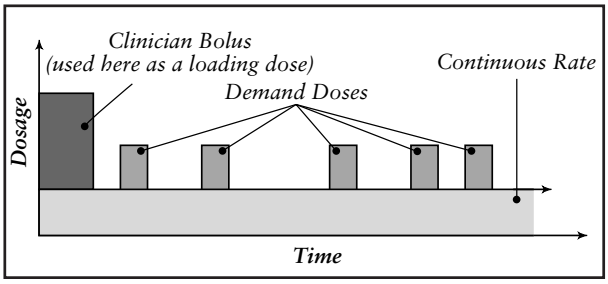


Figure 2. PCA mode delivery profile.

PCA Delivery Profile

The PCA (patient-controlled analgesia) delivery mode is used for therapies that require a continuous rate of infusion, patient-controlled demand doses or both, such as patient-controlled analgesia.

Continuous Rate Scroll Ranges

Units	Starting	Increment		Maximum
Milliliters	0.10	**0.10**		**30.00**
Milligrams & Micrograms	10% of concentration	**Mg only:** Values between 0.01 and 0.5:	0.01	**Concentration** x **30**
		Mcg only: Values between 0.1 and 0.5:	0.1	
		Values between 0.5 and 100:	0.1	
		Values between 100 and 1000:	1.0	
		Values greater than 1000:	10.0	

Table 1. PCA delivery mode: continuous rate scroll ranges.

	Milligrams			
Concentration	Demand Dose		Clinician Bolus	
mg/ml	increment	max.	increment	max.
0.1	0.01	0.99	0.01	2
0.2	0.02	1.98	0.02	4
0.3	0.03	2.97	0.03	6
0.4	0.04	3.96	0.04	8
0.5	0.05	4.95	0.05	10
1	0.05	9.9	0.05	20
2	0.10	19.8	0.10	40
3	0.15	29.7	0.15	60
4	0.20	39.6	0.20	80
5	0.25	49.5	0.25	100
6	0.30	59.4	0.30	120
7	0.35	69.3	0.35	140
8	0.40	79.2	0.40	160
9	0.45	89.1	0.45	180
10	0.50	99.0	0.50	200
11	0.55	108.9	0.55	220
12	0.60	118.8	0.60	240
13	0.65	128.7	0.65	260
14	0.70	138.6	0.70	280
15	0.75	148.5	0.75	300
20	1.00	198.0	1.00	400
25	1.25	247.5	1.25	500
30	1.50	297.0	1.50	600
35	1.75	346.5	1.75	700
40	2.00	396.0	2.00	800
45	2.25	445.5	2.25	900
50	2.50	495.0	2.50	1000
55	2.75	544.5	2.75	1100
60	3.00	594.0	3.00	1200
65	3.25	643.5	3.25	1300
70	3.50	693.0	3.50	1400
75	3.75	742.5	3.75	1500
80	4.00	792.0	4.00	1600
85	4.25	841.5	4.25	1700
90	4.50	891.0	4.50	1800
95	4.75	940.5	4.75	1900
100	5.00	990.0	5.00	2000

Table 2. Demand dose, clinician bolus scroll ranges, milligrams

	Micrograms			
Concentration	Demand Dose		Clinician Bolus	
mcg/ml	increment	max.	increment	max.
1	0.05	9.9	0.05	20
2	0.10	19.8	0.10	40
3	0.15	29.7	0.15	60
4	0.20	39.6	0.20	80
5	0.25	49.5	0.25	100
6	0.30	59.4	0.30	120
7	0.35	69.3	0.35	140
8	0.40	79.2	0.40	160
9	0.45	89.1	0.45	180
10	0.50	99.0	0.50	200
11	0.55	108.9	0.55	220
12	0.60	118.8	0.60	240
13	0.65	128.7	0.65	260
14	0.70	138.6	0.70	280
15	0.75	148.5	0.75	300
20	1.00	198.0	1.00	400
25	1.25	247.5	1.25	500
30	1.50	297.0	1.50	600
35	1.75	346.5	1.75	700
40	2.00	396.0	2.00	800
45	2.25	445.5	2.25	900
50	2.50	495.0	2.50	1000
55	2.75	544.5	2.75	1100
60	3.00	594.0	3.00	1200
65	3.25	643.5	3.25	1300
70	3.50	693.0	3.50	1400
75	3.75	742.5	3.75	1500
80	4.00	792.0	4.00	1600
85	4.25	841.5	4.25	1700
90	4.50	891.0	4.50	1800
95	4.75	940.5	4.75	1900
100	5.00	990.0	5.00	2000
200	10.00	1980.0	10.00	4000
300	15.00	2970.0	15.00	6000
400	20.00	3960.0	20.00	8000
500	25.00	4950.0	25.00	10000

Table 3. Demand dose, clinician bolus scroll ranges, micrograms

Milliliters			
Demand Dose		**Clinician Bolus**	
increment	max.	increment	max.
0.05	9.9*	0.05	20

Table 4. PCA delivery mode: Demand dose, clinician bolus scroll ranges, milliliters

*The maximum Demand Dose is 20 with software revision E or higher.

Specifications (Nominal)

General Pump Specifications

Resolution
Medication Cassette Reservoir or CADD® Administration Set, 0.050 ml per pump stroke nominal

Size
4.4 cm x 10.4 cm x 14.1 cm [1.7 in. x 4.1 in. x 5.6 in.] excluding cassette or other accessories

Weight
568 g [20 oz.] including 9 volt battery and empty 100 ml Medication Cassette Reservoir, excluding other accessories

Pump Alarms
Low battery power; depleted battery power; external power source low, faulty, depleted; pump stopped; pump fault; low reservoir volume; high delivery pressure; air in line; Air Detector faulty or detached (only with the use of the optional Air Detector); Air Detector Port Cover detached; delivery too slow; key stuck; cassette detached or unlocked; print failure, epidural cassette not used.

Bolus Volume at Occlusion Alarm Pressure
0.050 ml resolution administration sets/ Medication Cassette Reservoirs: <0.25 ml

Power Sources
9 volt alkaline or lithium battery such as DURACELL® Alkaline MN 1604 or ULTRALIFE® Lithium U9VL; CADD® External Power Source (EPS) Power Pack reorder number 21-3801; AC Adapter.

The expected life of a 9 volt battery is 12 hours at 100 ml/hour, or approximately 5 days at 10 ml/day (nominal). This estimate is based on laboratory tests conducted at room temperature using a new battery. Actual battery life will vary depending on the brand of battery, shelf life, temperature conditions, delivery rate, and frequency of screen display, backlighting and printing. It is recommended that a new 9 volt battery be kept available for replacement if necessary.

An internal battery powers the clock. When it is depleted, it cannot reliably maintain the clock time. This battery must be replaced by the manufacturer. The internal battery has an expected life of 5 years.

System Operating Temperature
+2°C to 40°C (36°F to 104°F)

System Storage Temperature
-20°C to 60°C (-4°F to 140°F)

Power Pack Charging Temperature
+10°C to 35°C (50°F to 95°F)

System DeliveryAccuracy
± 6% (nominal)

System Definition
System is defined as a CADD-Prizm® pump with an attached Medication Cassette Reservoir and CADD® Extension Set with integral anti-siphon valve, or an attached CADD® Administration Set with integral or add-on anti-siphon valve.

Delivery Specifications

Reservoir Volume
1 to 9999 or Not In Use; programmable in 1 ml increments, displayed in 0.1 ml increments.
Default: 1 ml

Units*
Milliliters (ml), milligrams (mg), micrograms (mcg).
Default: milligrams

Concentration

Mg/ml:

0.1 to 0.5 mg/ml in increments of 0.1
1 to 15 mg/ml in increments of 1 mg/ml
20 to 100 mg/ml in increments of 5 mg/ml
Default: 100 mg/ml

Mcg/ml:

1 to 15 mcg/ml in increments of 1 mcg/ml
15 to 95 mcg/ml in increments of 5 mcg/ml
100 to 500 mcg/ml in increments of 100 mcg/ml. Default: 500 mcg/ml

Continuous Rate
0 to 30 ml/hr (or the mg or mcg equivalent).
Default: 0 mg/hr (See Table 1 for Scroll ranges)

* If programmed to be part of pump programming screens in Biomed Toolbox.

Demand Dose
0 to 9.9 ml*
Delivery rate (Continuous Rate + Demand Dose): programmable from 40 to 125 ml/hr.
Default: 0 ml (See Table 2, 3 & 4 for Scroll ranges)

*The Maximum Demand Dose is 20 with software revision E or higher.

Demand Dose Lockout
5 minutes to 24 hours in the following increments:
- 1 minute for values between 1 and 20 minutes
- 5 minutes between 20 minutes and 24 hours

Default: 5 min

Set Delivery Limit
0.5 ml to 1000 ml (or the mg or mcg equivalent), or "No Limit":
0.01 from 0.01 to 0.1
0.1 from 0.1 to 100
1.0 from 100 to 1000
10.0 from 1000 to 10000
100.0 from 10000 to 100000
1000.0 from 100000 and up
Default: 0.5 ml or mcg or mg equivalent

Given
0 to 99999.99 in 0.01 unit increments.

Clinician Bolus
0.1 ml to 20.00 ml (or mg or mcg equivalent)
Delivery rate (Continuous Rate + Clinician Bolus): 125 ml/hr nominal (See tables 2, 3 & 4 for Scroll ranges)

High Pressure Alarm
18 ± 9 psi [1.24 ± 0.62 bar]

Air Detector Alarm
Single bubble greater than 0.100 ml

Options Specifications

Lock Level
LL0, LL1, LL2. Default: LL2

Epidural Mode
On or Off. Default: Off

Units*
Milliliters (ml), milligrams (mg), micrograms (mcg).
Default: milligrams

Time
00:00 to 23:59

Air Detector
Turned On or Turned Off. Default: On

Biomed Toolbox Specifications

Custom Concentrations
All individual mg or mcg concentration settings may be enabled or disabled (at least one concentration must be enabled).
Default: All On

Program Limits*
Maximum program limits may be programmed for Demand Dose, Continuous Rate, and Clinician Bolus.
Default: maximum program limits.

Dosing Limit*
Delivery Limit, a Maximum Doses per Hour, or neither. Default: Neither

Key Beeps
On or Off. Default: On

Res Vol Trip Point
1 to 999 ml in increments of 1 ml, or "Standard." Default: Standard

Res Vol Empty Alarm*
Single or Insistent alarm. Default: Single

Pump Stopped Alarm*
Beep or Two-tone alarm. Default: Beep

AutoLock
Not In Use, LL1 Key/Code, LL2 Key/Code, LL1 No Key or LL2 No Key. Default: Not In Use

PM (Preventive Maintenance) Reminder
1 to 24 months in 1 month increments, or "Not In Use." Default: Not In Use

Custom Lock Level Code
001 to 899 (excluding preset code) in increments of 1. Default: 061

Units Selection*
Program units to appear in the Programming Units screens. Default: All Programming Units

Units Location
Options, Program or Biomed Toolbox.
Default: Programming screens

* If programmed to be part of Options settings in the Biomed Toolbox.

Date Format
US Standard (mm/dd/yy) or European Standard (dd/mm/yy). Default: U.S. Standard

Custom Main Display

Display:

- Res Vol or Continuous Rate
- Power Source Always or Low 9 volt battery only

Default: Res Vol and Low 9V

Auto Review*

Select the automatic program review feature during the pump's power-up sequence. Default: On

- Dose Counters (0 to 999 Given and/or Attempted). Default: On
- Given. Default: On
- Doses Hour By Hour (up to 48 hours in increments of 1 hour). Default: Off
- Patient Review. Default: Off
- Pain Scale (subjective pain scale rating of 0 to 10 in increments of 1). Default: On
- Pain Scale Log (0 to 500 entries). Default: On
- Delivery Log (0 to 500 events). Default: Off
- Event Log (0 to 500 events). Default: Off
- New Patient Marker. Default: On

New Patient Marker*
Reports/No Clear, Power-up/No Clear, Reports/Clear, Power-up/Clear

Default: Reports/No Clear

Air Detector Required
Required or Not Required. Default: Not Required

Defaulting the Lock Level Code & Clinician Bolus Code

The standard Lock Level Code (061) can be changed to a customized code using the Biomed Toolbox Custom Lock Code feature. See the *Operator's Manual* supplied with the pump for instructions on customizing the Lock Level Code. If it becomes necessary to change a customized code back to the standard Lock Level Code, do the following:

1. Press the OPTIONS key until the Lock Level screen appears.
2. Press the ENTER key twice.
3. Scroll to 911.
4. Press the OPTIONS key.

Compatible Reservoirs and Administration Sets

- 50-ml or 100-ml Medication Cassette reservoir, used with the CADD® extension set with anti-siphon valve.
- CADD® administration set with integral anti-siphon valve, with or without bag spike (allows use of flexible plastic bag or sterile vial with injector)
- CADD® administration set with add on anti-siphon valve and bag spike (allows for gravity priming before attaching the add on anti-siphon valve)

Remote Dose Cord

Deltec provides a Remote Dose Cord for the PCA delivery mode. The push button switch is a Single Pole Double Throw (SPDT). When the Remote Dose Cord is attached to the pump, the patient may press the Remote Dose button to receive a Demand Dose. The clinician may use the Remote Dose button to deliver a clinician bolus. For easy access, the Remote Dose cord may be fastened to the patient's clothing or bedsheet with the attached clip.

NOTE:

To detach the Remote Dose cord from the pump, grasp the Remote Dose cord connector and pull back using a straight, steady motion. Do not twist or turn the connector, or use any instrument to remove it.

For additional specifications refer to the *Operator's Manual* provided with the product.

Note: The CADD-DIPLOMAT® PC Communications System batch programming mode must be used to change a customized code back to the standard lock level code with CADD-Prizm® PCS II pumps with software revision E or higher.

3 Batteries

Battery Compatibility

Recommended Batteries

Nine-volt alkaline or lithium batteries are recommended for use in the CADD-Prizm® pump. Carbon-zinc, mercury, nickel-cadmium, or zinc-air 9-volt batteries should not be used.

Battery Life

The CADD-Prizm® pump has been designed to provide optimal battery life. The expected battery life in the CADD-Prizm® pump depends on the following factors:

- Programmed delivery rate
- Operating temperatures
- Frequency of display backlighting
- Frequency of printing
- Battery type and brand
- Battery age

DURACELL® Alkaline Battery Life

The following tables may be used to predict typical alkaline battery life at different delivery rates when an alkaline battery is used in the CADD-Prizm® pump. As expected, battery life decreases as the delivery rate increases. These tables are based on laboratory tests using fresh DURACELL® alkaline batteries in CADD-Prizm® pumps while the pumps were operating at room temperature.

Actual battery life may be significantly shorter depending on the operating temperature and the storage conditions of the battery.

Battery life is shortened significantly at very low operating temperatures. For example, at 0°C (32°F), an alkaline battery will yield approximately 30% of its normal capacity.

Alkaline batteries do not need to be stored in a refrigerator. After four years of storage at 21°C (70°F), an alkaline battery retains approximately 86% of its original capacity. Battery life will be shorter if the battery is stored above room temperature. An alkaline battery stored at 43°C (110°F) will be down to approximately 80% of its capacity within one year.

Recommended storage conditions are 10°C to 25°C (50°F to 77°F) with no more than 65% relative humidity noncondensing.

The following tables are based on laboratory tests conducted at room temperature using fresh DURACELL® alkaline batteries and a CADD® administration set. Actual battery life will vary depending on the brand of battery, battery shelf life and temperature conditions.

ULTRALIFE® Lithium Battery Life

The following tables may be used to predict typical lithium battery life at different delivery rates when a lithium battery is used in the CADD-Prizm® pump. As expected, battery life decreases as the delivery rate increases. These tables are based on laboratory tests using fresh ULTRALIFE® lithium batteries in CADD-Prizm® pumps while the pumps were operating at room temperature.

Actual battery life may be significantly shorter depending on the operating temperature and the storage conditions of the battery. Lithium battery life is dependent upon the temperature and relative humidity of storage. Recommended storage conditions are less than 20°C (68°F) with a desiccant to ensure less than 10% relative humidity.

The following tables are based on laboratory tests conducted at room temperature using fresh ULTRALIFE® lithium batteries and a CADD® administration set. Actual battery life depends upon the brand of battery selected, the particular battery selected, battery shelf life, and temperature conditions. Deltec's testing indicates a large variability in battery life.

Continuous and PCA Delivery Battery Life (Max Delivery Rate PCA Mode 30 ml/hr)

Note: Results are without air detector.

Rate	Life	Volume
0.4 ml/hr	120 hrs	48 ml
10 ml/hr	86 hrs	860 ml
30 ml/hr	37 hrs	1110 ml
50 ml/hr	26 hrs	1300 ml
100 ml/hr	13 hrs	1300 ml
200 ml/hr	14 hrs	2800 ml
350 ml/hr	7 hrs	2450 ml

Table 4. 9-volt Alkaline-type batteries used with the CADD-Prizm® pump.

Rate	Life	Volume
0.4 ml/hr	212 hrs	85 ml
10 ml/hr	161 hrs	1610 ml
30 ml/hr	79 hrs	2370 ml
50 ml/hr	60 hrs	3000 ml
100 ml/hr	30 hrs	3000 ml
200 ml/hr	32 hrs	6400 ml
350 ml/hr	17 hrs	5950 ml

Table 5. 9-volt Lithium-type batteries used with the CADD-Prizm® pump.

Rate	Life	Volume
100 ml/hr	64 hrs	6400 ml
200 ml/hr	67 hrs	13400 ml
350 ml/hr	39 hrs	13650 ml

Table 6. EPS System used with the CADD-Prizm® pump.

4 Construction

The pump's housing is made of a special high impact plastic designed to reduce interference from electromagnetic fields and to dissipate electrostatic discharge. It is composed of two sections: the base and cover housing. The pump housing is sealed to ensure that the pump is water resistant. The battery compartment is not water resistant.

NOTE:

The CADD-Prizm® ambulatory infusion pump is water resistant, but not waterproof.

The battery compartment is accessed through a removable door on the side of the base housing. Within the battery compartment is space for the battery and the two battery contacts.

The Medication Cassette reservoir or the administration set is attached to the bottom of the pump by inserting the two hooks on the cassette into the mating hinge pins on the pump. The pump and the reservoir or the administration set are then placed in an upright position on a firm, flat surface. The reservoir or the administration set can be latched in place by inserting a coin in the slot on the pump's latching button, pushing the button in, and turning the button one-quarter turn counterclockwise. The reservoir or the administration set is locked into place by inserting a key into the pump's lock and turning the lock one-quarter turn counterclockwise.

NOTE:

The cassette lock must be unlocked before attempting to unlatch the disposable.

NOTE:

The Medication Cassette reservoir and the administration set are intended for single use only.

The keyboard, located on the front housing, is composed of nine membrane switches and is sealed against moisture. All of the keys contain domes to provide a tactile feel when the key is pressed. The keyboard keys are sensed by the pump's microprocessor.

The custom Liquid Crystal Display (LCD), also located on the front housing, shows the pump status and programmed settings. The dot matrix display consists of 21 character columns with 4 rows of characters, and is selected by the pump's microprocessor according to status conditions and keyboard entries.

The microprocessor and other circuitry which control the pump are located on two printed circuit boards. The microprocessor board contains the Central Processing Unit (CPU) and its associated circuitry, motor driver circuitry, and other miscellaneous circuitry. The LCD board contains the Liquid Crystal Display with its associated circuitry, and the backlight module with its associated circuitry.

The pumping mechanism subassembly contains the motor, gear train, camshaft, valves, expulsor, sensing disk, infrared light source, infrared detector, occlusion sensor, cassette sensors, lock and latch. Via the motor driver circuitry, the pump's microprocessor controls motor rotation.

Two external port connectors are utilized for communication and external power input. One of these connectors, the data in/out jack, is used for attachment of the Remote Dose cord. This enables the patient to use the Remote Dose cord to begin a Demand Dose.

This jack can also be connected via an interface cable to an external PC to view reports or to a printer to print reports. The second port is for external power connection. This port, the power jack, can receive input from either an AC adapter or the External Power Source rechargeable power pack.

Connections between the printed circuit boards are designed for ease of manufacturing and serviceability. The keyboard is connected to the microprocessor board via a flex circuit tail. Flexible circuitry and discrete wires connect the pumping mechanism, motor, and sensors to the printed circuit boards.

5 Theory of Operation

Keyboard Circuitry

The CADD-Prizm® PCS II pump is controlled by a microprocessor. The actions of the microprocessor are controlled by a program, which is contained in the memory.

Commands are issued to the microprocessor from the user via the nine keys on the keyboard and the Remote Dose cord. The keys on the keyboard feed individually into the Gate Array on the microprocessor board. A key closure applies a ground to the associated input of the Gate Array. Key debounce circuitry resident in the Gate Array provides a clean output signal to the microprocessor for the duration of the key closure. The microprocessor reads keyboard status by accessing special memory locations in the Gate Array.

The Remote Dose button consists of an SPDT switch with its own dedicated input to the microprocessor circuitry. The switch has a common input line and two output signal lines. The two signal lines are complementary such that one line is always logic high and the other is always low. When the Remote Dose button is pressed, both signal lines change to the alternate logic state. This redundancy prevents a single line failure from starting a dose delivery.

Data Memory EEPROM

Many settings of the pump's delivery and record keeping parameters are stored by the microprocessor in an Electrically Erasable Programmable Read Only Memory (EEPROM). Data to and from the memory is presented serially. Whenever the microprocessor uses data from the EEPROM, the data is checked for validity.

Battery Backed RAM

Additional settings of the pump's delivery and record keeping parameters are stored in a battery backed Random Access Memory (RAM). Battery backup is provided by two printed circuit board-mounted lithium batteries. These batteries are designed to provide a minimum of five years of memory retention during normal pump usage. Whenever the microprocessor uses data from the RAM, the data is checked for validity.

Time Base Circuitry

An accurate 3.6864 MHz timebase is provided by a quartz crystal. The 3.6864 MHz signal is connected to the microprocessor, where it is frequency-divided to access the program memory at a cycle rate of 921 kHz.

In addition, an accurate 32.768 kHz timebase is provided by a second quartz crystal. The 32.768 kHz signal is used for the real time clock.

LCD Circuitry

The high-impedance, low-power, special drive signals for the liquid crystal display are provided by the LCD-drivers. Each alpha or numeric character on the LCD is formed by darkening combinations of dots. Commands to display dots are issued via data bus commands to the LCD-drivers by the microprocessor.

The LCD circuit also contains a power supply which provides bias voltage to the LCD panel. This voltage controls the relative brightness of the characters. Additional circuitry allows the microprocessor to disable the LCD when not in use in order to conserve battery power.

A two brightness level LCD backlight is provided to improve LCD viewing under low light conditions. When the microprocessor enables the LCD, it also enables the low brightness backlight. Low brightness is used to conserve battery power. If the AC adapter is connected, the microprocessor will enable the high brightness backlight since this does not consume power from the battery.

The backlight automatically shuts off when the LCD is turned off.

LED Status Indicators

An amber and a green Light Emitting Diode (LED) are provided under the pump's front panel overlay to provide pump status to the user. Under software control, the LEDs can either flash at a low duty cycle or be on continuously. A flashing indicator typically indicates a normal mode of operation and a steady "on" indicator typically indicates a fault condition.

Flash PROM Technology

Program memory for the pump is stored in Flash Programmable Read Only Memory (Flash PROM). This type of memory allows modification of the contents without physically removing the device from the circuit board. Under certain circumstances, the program can also be downloaded through the I/O port on the side of the pump. Several layers of redundancy in the programming system prevent accidental erasing or modification of the PROM.

Gate Array Circuitry

The Gate Array contains circuitry which controls memory address decoding, keyboard debounce, Light Emitting Diode (LED) indicator status, LCD command buffering, Battery Backed RAM interface, and miscellaneous signal line buffering functions.

Audible Alarm Circuitry

Audible alarm circuitry consists of a piezo electric disk and independent oscillator. The disk flexes or bends in resonance with the output of the oscillator. The piezo disk is mounted to the pump housing to enhance sound level. The oscillator which drives the piezo disk is capable of providing two driving frequencies. The low frequency is in the range of 700 to 1500 Hz and the high frequency is in the range of 1600 to 2500 Hz. The microprocessor controls the audible alarm via control lines from the Gate Array. When the microprocessor selects both the low and high frequency control lines, the audible alarm enters a warble mode where it oscillates between the low and high frequency sound at a rate of 0.8 and 2 Hz. Low battery voltage detection and watchdog timer circuitry also have the ability to enable the audible alarm via the Gate Array.

Watchdog Timer Circuit

Watchdog timer circuitry is provided to monitor the status of the microprocessor and disable the motor and enable the audible alarm if the microprocessor fails to function properly. The microprocessor must strobe the watchdog circuit at least once every second in order to prevent the watchdog from performing its reset function. The reset output from the watchdog circuit is a pulse output. This acts to "jump start" the microprocessor. This unique feature allows the microprocessor to test the watchdog circuit on every power-up. By setting a flag in memory and not strobing the watchdog, the microprocessor can force a watchdog time-out. After being reset, the microprocessor checks the status flag to see if this was a time-out test. If so, the microprocessor continues normal power-up activities. If the reset occurred when the microprocessor was not expecting it, the microprocessor traps the event, sounds the audible alarm and displays an error message on the LCD.

Motor Driver/Motor Watchdog Circuit

Motor drive circuitry is composed of a series of power FET transistors, passive components, and two voltage comparators. Built into the motor drive circuitry is an RC timer which times how long the motor runs each time it is turned on. If the motor runs for more than an average of 4 seconds, the circuit will time out and disable the motor. A unique feature of this circuit is that control lines to and from the microprocessor circuit allow the microprocessor to perform a complete functional test of the motor drive circuit without running the motor. The microprocessor performs this test function every several minutes to assure its continued functionality. An input from the watchdog circuit prevents motor operation if the watchdog timer expires.

Rotation of the motor is sensed by the microprocessor via an infrared-sensitive photo

detector. An infrared light source is mounted so that its light beam illuminates the infrared detector. An opaque flag is mounted concentrically to the camshaft and rotates with it between the infrared light source and detector. When the flag interrupts the light beam, the output of the detector is sensed by the microprocessor via an input port bit. Power to the infrared LED light source is controlled by the motor driver circuit and is off when the motor is not running to conserve battery life.

In the microprocessor software, multiple checks are made on motion of the camshaft. When the motor is commanded to start, the infrared sensor must show that half a revolution has occurred within five seconds and that the motor has stopped when half a rotation was completed. In addition, no camshaft rotation can take place when the motor has not been commanded to run.

Power Circuitry

Power for the pump is normally supplied by a 9-volt alkaline battery, 9-volt lithium battery, or AC adapter. These types of batteries have a fairly low internal resistance over their discharge range, which will keep power supply noise low. Other types of batteries, such as carbon-zinc, exhibit high internal resistance, especially near depletion. A voltage drop across the internal resistance occurs when current is drawn by the motor during pump activations. This current is demanded in short pulses when the motor is first turned on and generates large spikes in the battery voltage. This noise can cause the low battery detection circuit to shut down the pump.

The motor driver circuit power is taken directly from the battery, but the microprocessor and its associated circuitry requires closely regulated and filtered 5-volt power which is supplied from the micropower voltage regulator. This regulator will supply 5-volt power until its input voltage is approximately 5.3 volts. After that point, the output of the regulator will follow the input voltage down.

Voltage Reference Circuit

A voltage reference circuit provides a constant DC voltage to the microprocessor Analog to Digital Converter (ADC). By reading this input and comparing the value to a predetermined range, the microprocessor can validate the accuracy of the 5-volt power supply. Variations in the 5-volt supply left undetected can result in inaccuracy in the low battery alarm set points and variations in other calculated values.

Voltage Trip Point*	CADD® Pump Status
>7.0V	No alarm
6.4–7.0V*	Transition to low battery condition; battery low message appears; 3 beeps every 5 min.†
6.0–6.6V*	Transition to depleted battery condition; battery depleted message appears; continuous alarm††
5.25–5.95V	Hardware reset occurs. Pump continues to indicate depleted battery condition.

* Voltage ranges are due to component tolerances. Actual trip values are guaranteed to be non-overlapping.

Table 12. CADD-Prizm® pump low battery conditions.

† The pump emits 3 beeps every 5 minutes, and the message “9 Volt Battery Low” appears on the pump’s display, indicating that the battery power is low, but the pump is operable.

†† The pump emits a continuous, variable-tone alarm, and the message “9 Volt Battery Depleted” appears on the display, the battery power is too low to operate the pump, and pump operation has stopped.

Pumping Mechanism

The pumping mechanism is linear peristaltic with two active valves. Pumping occurs when the expulsor presses on the reservoir pump tubing in sequence with the inlet and outlet valves. At rest, the outlet valve is pressing down fully on the tubing and the expulsor and inlet valve are retracted. (See Figure 7.)

When the microprocessor commands the mechanism to pump, the camshaft begins to rotate, thus controlling the following pump cycle:

1. The inlet valve closes.
2. In synchrony with the expulsor moving down to compress the tubing, the outlet valve opens, expelling 0.050 ml of fluid.
3. The outlet valve closes.
4. The inlet valve opens as the expulsor is retracted, causing fluid from the reservoir to again fill the pump tubing segment.
5. The camshaft rotation stops after half a revolution and the cycle is completed.

Pumping Characteristics

If the fluid path to the patient becomes blocked, the pump tubing will expand as pumping occurs. When there has been an amount of inflation corresponding to 124 ± 62 kPa (1.24 ± 0.62 bar, 18 ± 9 psi), the occlusion analog sensor trips, whereupon the microprocessor stops the pump mechanism and issues visual and audible alarms. Thus the maximum pressure which can be developed is 186 kPa (1.86 bar, 27 psi).

To deliver the amount of drug specified by the parameter settings, the pump's microprocessor causes the pump mechanism to deliver 0.05 ml fluid "pulses" timed according to the desired rate. At rates higher than 3 ml/hr, 2 pulses in succession will be given. Thus, to deliver 20 ml/hr, for example, the microprocessor solves these equations:

Mechanism activations per hr

= 20 ml per hr/0.1 ml per activation

= 20/0.1

= 200

Time (seconds) between activations

= 3600 sec per hr/number of activations per hr

= 3600/200

= 18

	Rate (ml/hr)	Volume Resolution (ml)
Cassette or Admin Set	0 - 3 3.1 - 125	0.050 0.100

The microprocessor uses its timer circuits to accurately time the 18 seconds (in this example) between mechanism activations. The timebase accuracy is ultimately determined by the 3.6864 MHz quartz crystal oscillator.

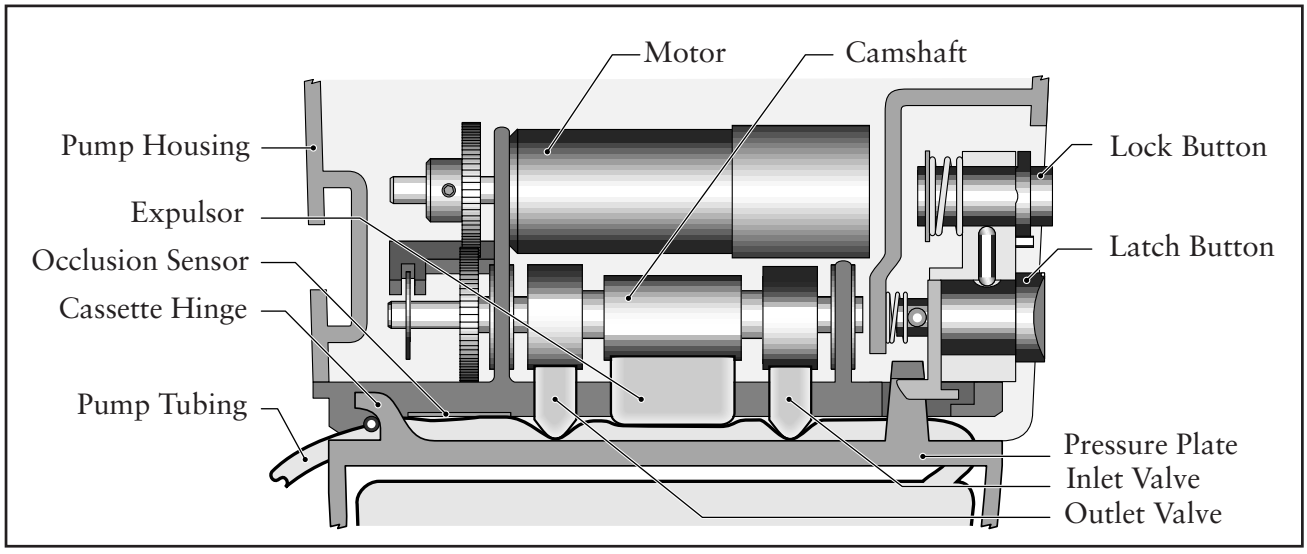


Figure 7. A simulated pumping mechanism in a CADD-Prizm® pump.

Air Detector

The air detector is designed to detect air in the outlet tubing fluid path. The air detector is detachable if not needed. The CADD-Prizm® pump automatically detects the presence of the air detector and will automatically turn the sensor on when powered up in LL0.

When the optional air detector is installed, the Biomed Toolbox feature allows the air detector to be "required" or "not required." When the air detector is not required, it can be "turned on" or "turned off" using the Options menu. When the air detector is required, the option for turning the air detector on or off will not be available. When the air detector is turned on, the pump will detect the presence of air in the outlet tubing fluid path. If the air detector settings are "not required" and "turned off," it will default to "turned on" each time the pump powers up in Lock Level 0.

The air detector is compatible with all of the reservoirs and sets indicated for use with the CADD-Prizm® pump, and all pump accessories. It is powered directly from the CADD-Prizm® pump and no additional power is required.

Specifications

The air detector will alarm when it senses a single air bubble greater than 100 microliters (0.1 milliliters.)

Construction

The air detector housing is made of a special high impact plastic and has a metalized film coating on the inside surface to reduce interference from electromagnetic fields. The air detector is composed of a single base compartment with a detachable door. It is sealed against the pump housing to ensure the overall assembly is water resistant. The air detector is mounted to the pump housing with two screws, and electrically connected with a ten pin connector.

Theory of Operation

The air detector consists of sensor electronics and two ultrasonic transducers positioned on opposite sides of the tubing. One transducer acts as an acoustic transmitter and the other as an acoustic receiver. Air detection occurs when air in the fluid path causes a reduction in the signal level to the receiver. When the signal is interrupted for a preset length of time, the sensing circuitry sends a signal to the microprocessor indicating air in the fluid path. To maximize the reliability of the system and to reduce false alarms, the transmitted signal is swept over a frequency range. This accommodates varying resonance frequencies of the transducer and reduces sensitivity to tubing tolerances and other mechanical variations.

Upstream Occlusion Sensor

Theory of Operation

The upstream occlusion sensor is a strain gauge device capable of detecting pressure changes in the disposable tubing set. This is accomplished by using a loading ball or sphere located on the bottom of the pump. This loading ball contacts the pump tubing when a tubing set is attached to the pump. Under normal operation, the pump tube pushes outward and applies a specified force on the sensor. When an upstream occlusion is present, the upstream tubing collapses pulling away from the sensor reducing the force on the sensor. It is this change of the force that indicates an upstream occlusion.

6 Safety Features and Fault Detection

Hardware Safety Features

Key hardware safety features include a watchdog timer circuit, motor driver and motor watchdog circuits, cassette 'type' sensor circuit, latch/lock sensor circuit, and a voltage detector circuit. Each safety circuit performs a unique function to insure the overall safety of the device. (See Figure 8.)

Watchdog Timer Circuit

The microprocessor must send an appropriate signal to the watchdog circuit at least once per second. If the microprocessor does not, the watchdog circuit will time out and shut down the pump controller.

Watchdog timer circuitry is provided to monitor the status of the microprocessor and disable the motor and enable the audible alarm if the microprocessor fails to function properly. The microprocessor must strobe the watchdog circuit at least once every second in order to prevent the watchdog from performing its reset function. The reset output from the watchdog circuit is a pulse output. This acts to "jump start" the microprocessor. This unique feature allows the microprocessor to test the watchdog circuit on every power-up. By setting a flag in memory and not strobing the watchdog, the microprocessor can force a watchdog time-out. After being reset, the microprocessor checks the status flag to see if this was a time-out test. If so, the microprocessor continues normal power-up activities. If the reset occurred when the microprocessor was not expecting it, the microprocessor traps the event, sounds the audible alarm and displays an error message on the LCD.

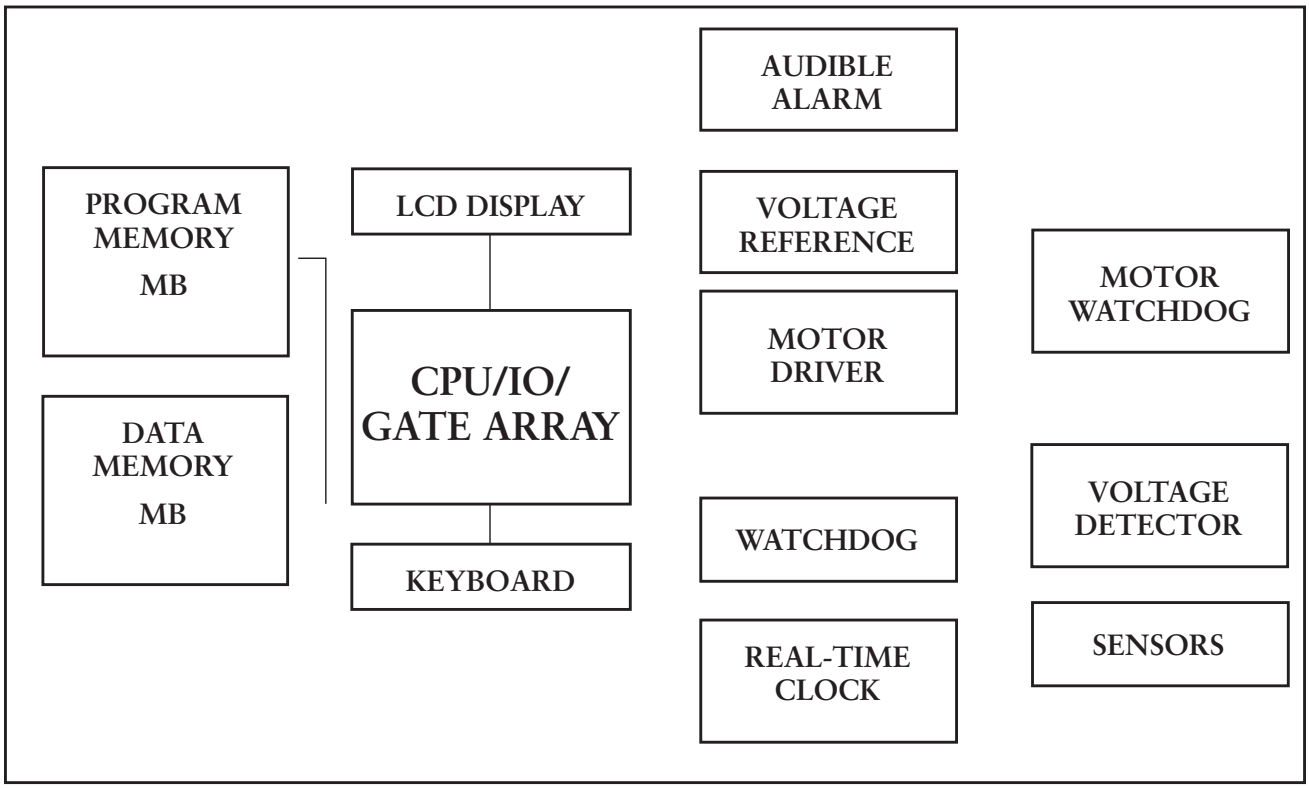


Figure 8. CADD-Prizm® pump hardware block diagram.

Motor Driver/Motor Watchdog Circuit

Motor drive circuitry is composed of a series of power FET transistors, passive components, and two voltage comparators. Built into the motor drive circuitry is an RC timer which times how long the motor runs each time it is turned on. If the motor runs for more than an average of 4 seconds, the circuit will time out and disable the motor. A unique feature of this circuit is that control lines to and from the microprocessor circuit allow the microprocessor to perform a complete functional test of the motor drive circuit without running the motor. The microprocessor performs this test function every several minutes to assure its continued functionality. An input from the watchdog circuit prevents motor operation if the watchdog timer expires.

Cassette 'Type' Sensor Circuit

The cassette 'Type' sensor system consists of three pins protruding from the button of the pump mechanism that interface to the attached administration set and associated circuitry. Each type of administration set designed to work with the CADD-Prizm® pump contains a unique 'code' programmed into the set via nubs molded into the plastic. When a set is latched to the pump, the nubs press against the pins in the pump mechanism in a pattern unique to that set type. Optical detectors and electronic circuitry on the circuit board encode this pattern and report the information to the microprocessor. This feature allows automatic rate selection dependent on the type of set attached. This system also acts as a safety feature to detect a damaged or detached set. If, during operation, the microprocessor detects all pins extended, the pump will enable audible and visual alarms and stop delivery. Redundancy in the pattern prevents single fault failures from causing over or under delivery of fluid. Additional circuitry allows these sensors to be turned on and off by the microprocessor to conserve battery power. Additionally, control of sensor power allows the microprocessor to test the sensor inputs in both the powered and unpowered states, thus allowing detection of sensor fault conditions. Care should be taken not to damage these sensor pins.

Latch/Lock Sensor Circuit

Latch and Lock sensors allow the microprocessor to detect the positions of the latch and lock buttons. This prevents attempted fluid delivery when the set is not correctly latched to the pump. In addition, it allows the microprocessor to stop fluid delivery and enable audible and visual alarms if the set is unlatched during fluid delivery. Opposing infrared transmitters and receivers on both the latch and lock buttons allow the microprocessor to detect their open and closed positions. Additional circuitry allows these sensors to be turned on and off by the microprocessor to conserve battery power. Additionally, control of sensor power allows the microprocessor to test the sensor inputs in both the powered and unpowered states, thus allowing detection of sensor fault conditions.

Voltage Detector Circuit

Low voltage detection is performed by part of the watchdog circuit and by the microprocessor via software. Three low voltage levels are detected. The first two levels are detected by software and the third by hardware. The first level to be reached is the Low Battery Warning threshold which occurs when the battery voltage decays to a nominal value of 6.8 volts. An Analog to Digital Converter (ADC) built into the microprocessor allows the microprocessor, via software, to monitor the battery voltage. At the Low Battery Warning threshold, the microprocessor enables a periodic series of beeps and displays a low battery warning message on the LCD. As the battery voltage reaches a nominal value of 6.3 volts, the software disables delivery, places a battery depleted message on the LCD, and enables a constant two-tone audible alarm. When the battery voltage decays to a nominal value of 5.6 volts, a hardware reset circuit is triggered which places the microprocessor in reset. This prevents ambiguous microprocessor operation when the battery voltage continues to decay. The hardware reset continues until the battery is completely discharged or until it is removed. Once the pump controller goes into low battery shutdown, only replacing the old battery with a fresh one will clear the condition.

Software Safety Features

Hardware-related Software Safety Features

Program Memory Check

At power up and at regular intervals thereafter, the program memory is tested by calculating a Cyclic Redundancy Code (CRC) on the program and then comparing it with the CRC stored with the program. If the stored and calculated CRCs do not match, the software will turn on a continuous two-tone audible alarm and stop all drug delivery.

RAM Memory Check

At power up, the random access memory is checked. A particular bit pattern is written to and read from each address in the RAM. If the read data is different from the written data, the software will turn on a continuous two-tone audible alarm and stop all drug delivery.

Motor Circuit Check

At power up and at regular intervals thereafter, the motor circuit is checked to ensure that no power is being applied to the motor unless the motor is actually on. If the software detects power being applied to the motor at any other time, it will sound a continuous two-tone audible alarm and will no longer attempt to deliver medication. During every pump activation, the software checks to see whether the motor completes one activation. If the motor fails to turn, or fails to complete a cycle, the software will turn on a continuous two-tone audible alarm and stop all drug delivery.

Keyboard Encoder Check

Every time the software receives data from the keyboard encoder, it is checked. If the data is not of the proper form, the software will turn on a continuous two-tone audible alarm and stop all drug delivery. The DOSE key has two independent signal lines to prevent single fault failures.

Data Handling Software Safety Features

Data Stored in RAM

Before use, data associated with delivery and stored in RAM is tested by calculating a CRC on the data and then comparing it with the CRC stored with the data. If the stored and calculated CRCs do not match, the software will turn on a continuous two-tone audible alarm and stop all drug delivery.

Data Stored in EEPROM

Before use, data associated with delivery and stored in EEPROM is tested by calculating a CRC on the data and then comparing it with the CRC stored with the data. If the stored and calculated CRCs do not match, the software will turn on a continuous two-tone audible alarm and stop all drug delivery.

Data Stored in NOVRAM

Before use, data associated with delivery and stored in NOVRAM is tested by calculating a CRC on the data and then comparing it with the CRC stored with the data. If the stored and calculated CRCs do not match, the software will turn on a continuous two-tone audible alarm and stop all drug delivery.

Data Used in Calculations

Calculations on data used in some way to control the delivery of drug are performed redundantly. The two calculated values are then compared. If the two values do not match, the software will turn on a continuous two-tone audible alarm and stop all drug delivery.

Timer Data Registers

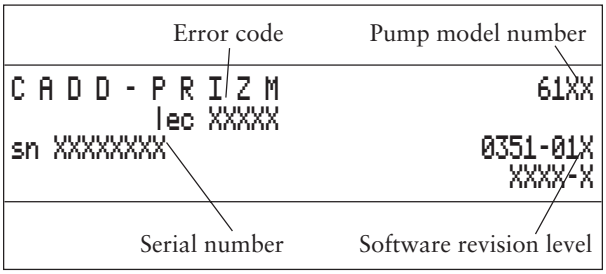
The data stored in the timer control register is checked at regular intervals. If the data is not correct, the software will turn on a continuous two-tone audible alarm and stop all drug delivery.

7 Hardware and Software Fault Detection

Overview

If the CADD-Prizm® pump displays an error code, a hardware or software fault has been detected by the microprocessor, and the pump should be returned for servicing.

When hardware or software faults are detected by the microprocessor, pump operation stops and a continuous, audible alarm will be activated as well as the amber warning LED. An error message will be displayed. On the next power up, the error code will again be displayed with the software level (see illustration below). If the error detected was a data fault, the pump will be in Lock Level 2, and all other programmed functions will have default values. (See the pump's *Operator's Manual* for specific defaults.)



Order of Error Code Events

1. There is a continuous two-tone audible alarm, a continuous amber indicator light, and the display will read

   Error Detected
   E(XXXXX)

NOTE:

"XXXXX" is a 5-digit code.

2. To silence the error code alarm, remove the battery.
3. At the next power-up, the last error code (lec) will be visible on the display. The microprocessor will also record an error code in the Event Log. The description "Error Detected" along with five digits will appear in the LCD in the Event Log. These five digits will remain in memory and will appear on the Event Log record until 500 data writes have occurred or until the mode has been changed. (See "Testing Procedures" starting on page 23 of this manual for detailed instructions regarding the power-up check.) Thus, there is always a record of the last internal fault detected by the microprocessor.

8 Cleaning and Inspection Procedures

Inspection Recommendation

Deltec recommends annual functional inspection on the CADD-Prizm® pump. The following inspection and testing procedures should be performed annually to verify function and accuracy.

NOTE:

Persons performing the following tests and procedures should be familiar with the Deltec CADD-Prizm® pump. Please read the *Operator's Manual* supplied with the pump before proceeding.

WARNING:

CADD® pumps are sealed units. A broken or damaged seal will, therefore, be considered conclusive evidence that the pump has been misused and/or altered, which voids any and all warranties. All service and repair of CADD® pumps must be performed by Deltec or its authorized agents.

Cleaning

CAUTION:

- **Do not immerse the pump in cleaning fluid or water. Do not allow solution to soak into the pump, accumulate on the keypad, or enter the battery compartment.**
- **Do not allow solution to enter the data in-out jack or the power jack. Make sure the jack covers are closed before cleaning.**
- **Do not expose the open air detector port area of the pump or the connector opening on the air detector to foreign material, moisture or cleaning fluids. If an air detector is not installed on the pump, make sure the air detector port cover is securely attached before cleaning.**
- **Do not clean the pump with acetone, other plastic solvents, or abrasive cleaners.**

Use any of the following solutions to clean the pump and accessories:

- Soap solution
- Benzalkonium chloride concentrate (0.13%)
- Glutaral concentrate, USP (2%)
- 10 percent solution of household bleach (one part household bleach to nine parts water)
- Alcohol, USP (93%)
- Isopropyl Alcohol, USP (99%)
- PDI – Super Sani-Cloth®
- Mada Medical – MadaCide

1. Dampen a soft, lint-free cloth with cleaning solution. Apply the solution to exterior surface of the pump or accessory. ***Do not allow the solution to soak into the pump or accessory.***
2. Wipe the entire surface dry with another soft, lint-free cloth. Allow the pump to dry completely before use.

Visual Inspection

- Visually inspect the pump for any damage to the LCD, occlusion sensor seals, valves and expulsor, reservoir hinge area, latch, lock, cassette sensors (3), keyboard, indicator lights, power jack, data in/out jack, air detector port cover or air detector, and housing. If any damage is noted, the pump should be returned for service.
- Check the battery door for proper operation. It should not be broken or damaged. The mating tabs on the pump housing should not be broken or damaged.
- Examine the battery compartment for damage. If the battery contacts appear corroded, clean them with a cotton swab and isopropyl alcohol. If the battery contacts appear to be bent or pushed in, straightening may be possible with a small screwdriver or other suitable tool. Care must be taken so as not to damage the pump housing or to incur further damage to the contacts.

Mechanical Inspection

- Press each key on the keyboard. Each key should have a distinctive dome feeling. The keys should not feel flat.
- Attach the battery door. The battery door should fit snugly in place when it is closed on the pump.
- Attach either a 50- or 100-ml Medication Cassette reservoir or a CADD® administration set to the pump. Check for smooth operation and a definite "feel" when the latch pulls the reservoir or administration set firmly against the bottom of the pump. The mark on the latch should be aligned with the solid dot.
- Lock the device by inserting a key into the lock and turn counterclockwise until the mark lines up with the solid dot.
- Gently twist and pull on the cassette to make sure it is firmly attached.

NOTE:

In the PCA delivery mode, the cassette must be locked in order to start the pump.

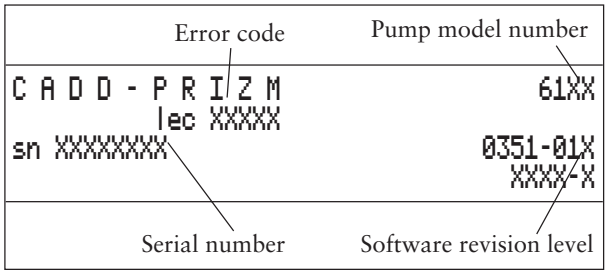
9 Testing Procedures

Functional Testing

The Power-up Check, Latch/Lock Check and Cassette Sensor Check using a Medication Cassette reservoir or CADD® administration set can be performed with the pump in any of the four delivery modes.

Power-up Check

- Insert a battery in the pump and observe the LCD during power up.



The number values may vary depending on the current mode and software revision.

- If "lec XXXXX" (last error code with 5 digit number) appears on the display prior to the pump reviewing the current program settings, the pump has experienced an electrical or mechanical fault and should be returned for service. If no error message is immediately shown, the pump has powered up normally. The pump should sequentially display all of the programmed values. The words "Self Test Complete" should appear, then the text "Power Up Successful" with six audible beeps. Continue with the Latch/Lock check.

Latch/Lock Check

- Attach a 50- or 100-ml Medication Cassette reservoir or a CADD® administration set to the pump. The mark on the latch should be aligned with the solid dot. The display should show that the reservoir or administration set is latched. See Table 13.
- Lock the device by inserting a key into the lock and turning counterclockwise until the mark lines up with the solid dot. The display should show "Cassette Locked."

If the Epidural mode is NOT turned on in the Options Menu:	
Reservoir Latched	VIEW to continue
Admin set Latched	Upstream Sensor On. VIEW to continue
If the Epidural mode is turned on in the Options Menu:	
Reservoir Latched	Is epidural reservoir attached Press YES or NO
Admin set Latched	Upstream Sensor On. Is epidural admin set attached? <Press YES or NO>
• Select Yes	

Table 13.

- Unlock the device by inserting a key into the lock and turning clockwise until the mark lines up with the open dot. The display should show "Cassette Unlocked."
- Unlatch the reservoir by inserting a coin into the latch slot and turning clockwise until the mark lines up with the open dot. The display should show "Cassette Unlatched / Close Clamp to Prevent Free Flow."

Cassette Sensor Check

- Attach a 50- or 100-ml Medication Cassette reservoir to the pump. Latch the cassette to the pump. The display should show "Reservoir latched." NOTE: The message displayed depends on the type of reservoir or administration set attached. See Table 13.
- Lock the device by inserting a key into the lock and turning counterclockwise until the

mark lines up with the solid dot. The display should show "Cassette Locked."

- Unlock the cassette. The display should show "Cassette Unlocked." Unlatch the cassette. The display should show "Cassette Unlatched / Close Clamp To Prevent Free Flow."
- Remove the 50- or 100-ml reservoir and attach a CADD® administration set to the pump. Latch the cassette to the pump. The display should show "Admin Set Latched." (See table 13)
- Lock the device by inserting a key into the lock and turning counterclockwise until the mark lines up with the solid dot. The display should show "Cassette Locked."
- Unlock the cassette. The display should show "Cassette Unlocked." Unlatch the Administration Set. The display should show "Cassette Unlatched/Close Clamp To Prevent Free Flow."

The following three checks (LCD, motor and gear train, and Reservoir Volume is Zero alarm) should be performed in the sequence shown.

LCD Check

- Remove and reinsert the battery. After a few seconds, the LCD will display all off pixels (dots) followed by all on pixels. Examine the LCD for missing dark or light pixels.
- Program the pump to the following parameters:

Units:	Milligrams
Concentration:	1.0 mg/ml
Continuous Rate:	30.0 mg/hr
Demand Dose:	0.0 mg
4 Hour Delivery Limit:	No Limit
Reservoir Volume:	2.0 ml

- Press the VIEW/SILENCE key until units is displayed on the LCD. Press the YES or NO key until milligrams is displayed and press the ENTER key. Select the Concentration of 1.0 mg and press the ENTER key. Select the Continuous Rate of 30.0 mg/hr, then press the ENTER key. Select the Demand Dose of 0.0 mg, then press the ENTER key. Select the 4 hour limit to "No Limit", then press the ENTER key. Select the Reservoir Volume of 2.0 ml, then press the ENTER key.

Motor and Gear Train Check

- Attach either a 50- or 100-ml Medication Cassette reservoir or CADD® administration set to the pump. Latch and lock the cassette.
- Press the PRIME/BOLUS key. Press and hold the YES key. The pump should begin to prime. While priming the pump, listen to the motor for excessive noise or grinding sounds. Continue to hold the YES key for ten double activations, or 1.0 ml, and then release the PRIME/BOLUS key. The display should show "Continue Priming? Press YES or NO." Press the NO key. Then press the VIEW/SILENCE key until the Reservoir Volume screen appears. The reservoir volume should show 1.0 ml.

Reservoir Volume is Zero Alarm Check

- Press the PRIME/BOLUS key. Press and hold the YES key. The pump should prime ten double activations and then stop. The pump will alarm and display "Reservoir Volume is Zero." Press the VIEW/SILENCE key.
- Reprogram the reservoir volume to 1.0 ml. Press the VIEW/SILENCE key until Reservoir Volume is displayed on the LCD. Press the YES or NO key until 1.0 ml is displayed. Then press the ENTER key.

NOTE:

The remaining testing procedures should be performed using a 50- or 100-ml Medication Cassette reservoir containing fluid and a primed extension set with anti-siphon valve or a primed CADD® administration set with anti-siphon valve.

Starting/Stopping the Pump

- Check the STOP/START key by pressing it. "Start the Pump?" should be displayed. Press the YES key. The display should show "Starting Pump" followed by a review of the programmed parameters. The main screen should appear with "RUNNING" in the display, and the green LED indicator light should blink every 3 seconds.

- To stop the device, press the STOP/START key. When the message "Stop the Pump?" appears, press YES. STOPPED appears in the display and the amber LED indicator light blinks.

Activation Timing Check

- Check the activation timing by programming the pump with the following values:

Units:	Milligrams
Concentration:	1.0 mg/ml
Continuous Rate:	30.0 mg/hr
Demand Dose:	0.0 mg
Delivery Limit	No Limit
Reservoir Volume:	1.0 ml

- Press the STOP/START key. Press the YES key. "Starting Pump" should appear on the display. The pump should sequentially display all of the programmed values. Start a timer at the first motor activation.
- Count the activations. One activation should occur every twelve seconds. Approximately one minute fifty seconds (1:50) and ten activations later, the RES VOL alarm should occur. The display should show "Reservoir Volume is Zero".

Remote Dose Cord Check

- Check the Remote Dose Cord button operation by programming the pump with the following values:

Units:	Milligrams
Concentration:	1.0 mg/ml
Continuous Rate:	0.0 mg/hr
Demand Dose:	1.0 mg
Demand Dose Lockout:	0 hrs 5 min
Delivery Limit	No Limit
Reservoir Volume:	10.0 ml
Dose Counters:	0/0 (Press the ENTER key to clear in the REPORTS menu)
Milligrams Given:	0.00 mg (Press the ENTER key to clear in the REPORTS menu)

- Press the STOP/START key. Press the YES key. The pump should sequentially display all of the programmed values.
- After RUNNING appears on the display, press the Remote Dose Cord button and note the time. The pump should beep twice and begin to deliver. Count the number of pump activations. The pump should make ten double activations. After ten double activations, the display should show a reservoir volume of 9.0 ml. Press the Remote Dose Cord button two more times within the next 5 minutes. The pump should not deliver and the message "Dose Not Delivered Dose Locked Out" should be displayed.

Doses Given and Doses Attempted Check

- Stop the pump by pressing the STOP/START key, then the YES key. Press the REPORTS key to advance to the Dose Counters report. The display should show 1/3. (If the above steps have not been followed exactly, different values may appear.)
- Press the ENTER key. The display should now show 0/0.

MG GIVEN Report Check

- Press the REPORTS key to advance to the Milligrams Given report. The display should now show 1.0 mg if the Remote Dose cord was tested. (If the above steps have not been followed exactly, different values may appear.)
- Press the ENTER key. The display should now show 0.0 mg.

Air Detector Test (if applicable)

This test will verify the function of the optional air detector. To perform this test, the CADD-Prizm® pump must have an air detector installed and the air detector must be turned on. The previous program from the DOSE key check (page 26) can be used to perform this test.

- Attach an empty Medication Cassette reservoir or CADD® administration set to the pump.
- Latch and lock the set to the pump.
- Open the air detector door and thread the tubing through the groove.

- Close the door making sure the tubing does not get pinched or kinked.
- Start the pump.
- The pump should respond with a continuous two-tone alarm and the display should read:

  Air in line detected
  Pump will not run
  VIEW to silence

- Press VIEW/SILENCE to silence the alarm, and remove the Medication Cassette reservoir or CADD® administration set.
- Now attach a Medication Cassette reservoir containing fluid and a primed extension set with anti-siphon valve, or a primed CADD® administration set with anti-siphon valve to the pump. Make certain there is no air in the fluid path.
- Latch and lock the set to the pump.
- Open the air detector door and thread the tubing through the groove.
- Close the door making sure the tubing does not get punched or kinked.
- Start the pump.
- Deliver a demand dose. (NOTE: five minutes must have passed since the delivery of the last demand dose.)
- The pump should deliver the dose without an air detection alarm.

Occlusion Accuracy Tests

This manual provides two testing options for the Occlusion Pressure Range Test and the Accuracy Test. Only one option needs to be performed. It is not necessary to perform both Option 1 and Option 2.

Downstream Occlusion Pressure Range Test (Option 1)

Description

Pressure is generated by activating the pumping mechanism with an attached filled, clamped Medication Cassette reservoir. The pump is started and a Demand Dose is given until the high pressure alarm sounds.

Equipment needed

50- or 100-ml Medication Cassette reservoir containing water.

Procedure

1. Insert a battery and wait for the pump to power up.
2. Attach a Medication Cassette reservoir containing water to the pump. Latch and lock the cassette.
3. Prime the Medication Cassette reservoir tubing. The tubing should be filled with fluid to the end of the luer lock connector. The system ***must*** be free from air bubbles for this test.
4. Close the slide clamp on the distal end of the tubing near the female luer of the Medication Cassette reservoir.
5. Program the pump to the following parameters:

Units:	Milligrams
Concentration:	1.0 mg/ml
Continuous Rate:	0.0 mg/hr
Demand Dose:	1.0 mg
Demand Dose Lockout:	0 hrs 5 min
Delivery Limit	No Limit
Reservoir Volume:	10.0 ml

6. Start the pump. When the pump is running, activate a Demand Dose, noting when the high pressure alarm is activated.
7. The pump should alarm when the pump delivers between 1 and 2 activations.

Downstream Occlusion Pressure Range Test (Option 2)

Description

An adjustable metered pressure source is connected to the Medication Cassette reservoir tubing. The pressure is slowly increased until the high pressure alarm sounds.

Equipment needed

- Pressure gauge, 30 psi ± 1 psi.
- Pressure vessel, partially filled with water.
- Pressure regulator, 30 psi.
- 50 or 100 ml Medication Cassette reservoir containing water.

Procedure

1. Insert a battery and wait for the pump to power up.
2. Attach a Medication Cassette reservoir to the pump. Latch and lock the cassette.

NOTE:

The pressure from the source must be zero when the cassette is attached.

3. Assemble the apparatus as shown in Figure 9.

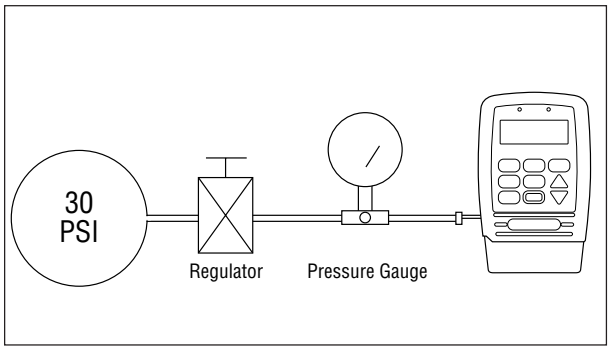


Figure 9. Occlusion test set-up.

4. Connect the Medication Cassette reservoir outlet tube to the metered pressure source.

NOTE:

Do not use a CADD® extension set with anti-siphon valve.

5. Start the pump and run at 30 ml/hr.
6. Slowly increase the back pressure, noting when the high pressure alarm is activated. NOTE: The pressure may be increased rapidly to 8 psi, after which the pressure should be increased at 3 psi/min or less until the alarm sounds.
7. The high pressure alarm should sound between 9 and 27 psi (18±9 psi).

Upstream Occlusion Sensor Test

Description

The tubing between the fluid reservoir and the pump is occluded while the pump is running until the occlusion alarm sounds.

Equipment needed

- CADD® administration set with anti-siphon valve.
- Tubing clamp (slide clamp or hemostat)

Procedure

1. Spike an appropriate standard I.V. bag.
2. Prime the entire fluid path.
3. Program the pump to deliver a continuous rate of 30 ml/hr.
4. Start the pump.
5. Clamp the tubing halfway between the fluid reservoir and the pump.
6. The pump should alarm within three activations after clamping the tubing.

Note: Make sure the upstream occlusion sensor is turned on in the Biomed Toolbox.

Accuracy Testing

Accuracy testing may be performed in any delivery mode. This manual shows an example of delivery accuracy testing with the pump in the PCA delivery mode.

Gravimetric Accuracy Testing (Option 1)

Description

A Medication Cassette reservoir is partially filled with water and weighed. The reservoir is then attached to the pump and the pump is set to deliver a certain amount of water. The reservoir is then removed and weighed again. The amount of water delivered is compared to the amount that the pump should have delivered.

Nominal system accuracy is given in the technical specifications section for the pump. That is, under the test conditions described below, the accuracy of the pump and reservoir will be nominal with a 90% confidence level. The nominal test conditions are as follows: degassed water at 25 ± 5°C without back pressure.

Equipment needed

- 50- or 100-ml Medication Cassette reservoir.
- 50- or 60-ml syringe.
- CADD® extension set with anti-siphon valve
- A balance accurate to 0.1 g.
- 40 ml of room temperature water.

Procedure

1. Fill the 50- or 60-ml syringe with 40 ml of water. Transfer the water into a Medication Cassette reservoir.
2. Remove any air from the Medication Cassette reservoir by aspirating the air with the syringe. Attach the CADD® extension set with anti-siphon valve. Prime the tubing so it is filled with fluid to the end of the extension set luer lock connector.
3. Secure the clamp as close to the extension set luer lock connector as possible. This should assure a minimum water loss from the tubing when the syringe is removed.
4. Weigh the entire reservoir/extension set assembly and record the weight. This is the pre-delivery weight. (This weight includes the empty Medication Cassette reservoir, extension set, and weight of the water.)
5. Attach the Medication Cassette reservoir to the pump. Program the reservoir volume to 20 ml. Now press the ENTER key. This value is the intended delivery volume. (One ml of water at 20°C weighs 1 gram.) Open the clamp.
6. With the pump in Lock Level 0, program a continuous rate of 0 ml/hr and a dose of 1.0 ml (but do not deliver a Demand Dose). Start the pump and deliver a clinician bolus of 20 ml.
7. Again, secure the clamp as close as possible to the end of the extension set luer lock connector. Remove the Medication Cassette reservoir from the pump and weigh the entire reservoir/extension set assembly. This is the **postdelivery weight**.
8. Calculate the difference in weight between the predelivery weight and the postdelivery weight. This is the **weight of the amount delivered**.
9. Find the difference between the volume of the amount delivered and the intended delivery volume. This is the **inaccuracy volume**.
10. Divide the inaccuracy volume by the intended delivery volume and multiply by 100. This is the **accuracy error percentage** (See Table 14).

Pre-Delivery Weight	Post Delivery Weight	Weight of Amount Delivered	Intended Delivery Volume	Inaccuracy Volume	Accuracy Error	Accuracy Error Percentage
61.1 g	41.6 g	19.5 g = 19.5 ml	20 ml	-0.5 ml	-0.5 ml ÷ 20.0 ml = -0.025	-0.025 x 100 = -2.5%

Table 14. Gravimetric percentage calculation

11. If the accuracy error percentage is greater than ± 6%, repeat the test with a new reservoir. If the pump fails a second time, call Deltec's Customer Service Department.

EXAMPLE:

Predelivery Weight:	61.1 g
Postdelivery Weight:	- 41.6 g
Weight of Amount Delivered:	**19.5 g = 19.5 ml**
Volume of Amount Delivered:	19.5 ml
Intended Delivery Volume:	- 20.0 ml
Inaccuracy Volume:	**– 0.5 ml**
Inaccuracy Volume:	– 0.5 ml
Intended Delivery Volume:	÷ 20.0 ml
Accuracy Error:	**-0.025 ml**
Accuracy Error:	-0.025 x 100.00
Accuracy Error Percentage:	**–2.5%**

Volumetric Accuracy Testing (Option 2)

Description:

A predetermined amount of water is delivered into a collection device such as a burette or graduated cylinder. The amount of water delivered is compared to the amount that the pump should have delivered.

Nominal system accuracy is given in the technical specifications section for the pump. That is, under the test conditions described below, the accuracy of the pump and reservoir will be nominal with a 90% confidence level. The nominal test conditions are as follows: degassed water at 25 ± 5°C without back pressure.

Equipment needed:

- 50- or 100-ml Medication Cassette reservoir
- 50- or 60-ml syringe
- CADD® extension set with anti-siphon valve
- A fluid collection device such as a burette or a class A 25 ml capacity graduated cylinder
- 40 ml of room temperature water

Procedure:

1. Fill the 50- or 60-ml syringe with 40 ml of water. Transfer the water into a Medication Cassette reservoir.
2. Remove any air from the Medication Cassette reservoir by aspirating the air with the syringe. Attach the CADD® extension set with anti-siphon valve. Prime the tubing so it is filled with fluid to the end of the extension set luer lock connector.
3. Attach the end of the extension set to the fluid collection device.
4. Attach the Medication Cassette reservoir to the pump. Program the reservoir volume to 20 ml. This is the **intended delivery volume**. Open all clamps.
5. Program a continuous rate of 0.0 ml/hr and a Demand Dose of 1.0 ml (but do not deliver a Demand Dose). Start the pump and deliver a clinician bolus of 20 ml.
6. When delivery is complete, record the volume of fluid delivered. This is the **actual delivery**.
7. Find the difference between the volume of the amount delivered and the intended delivery volume. This is the **inaccuracy volume**.

8. Divide the inaccuracy volume by the intended delivery volume and multiply by 100. This is the **accuracy error percentage**. (See Table 15.)

9. If the accuracy error percentage is greater than ±6%, repeat the test with a new reservoir. If the pump fails a second time, call Deltec's Customer Service Department.

Intended Delivery Volume	Actual Delivery Volume	Inaccuracy Volume	Accuracy Error	Accuracy Error Percentage
20 ml	19.5 ml	-0.5 ml	-0.5/20.0 ml =-0.025	-0.025 x 100 = ±2.5%

Table 15. Volumetric percentage calculation

CADD-Prizm® Pump Cleaning and Functional Testing Checklist

The following checklist is provided as a guide only to assist in establishing documentation of cleaning and functional testing for the CADD-Prizm® pump. If service is provided, fill out this sheet and return it with the device.

Serial # _____ Reference Number _____ Date _____

(Refer to the Technical Manual procedures.)

I. Cleaning Completed ☐ Yes ☐ No

II. Visual Inspection

- ☐ LCD
- ☐ Occlusion Sensor Seals
- ☐ Valves and Expulsors
- ☐ Reservoir Hinge Area
- ☐ Latch
- ☐ Lock
- ☐ Cassette Sensors (3)
- ☐ Keyboard
- ☐ Indicator Light
- ☐ Power Jack
- ☐ Data In/Out Jack
- ☐ Air Detector or Port Cover
- ☐ Pump Housing
- ☐ Battery Door
- ☐ Battery Compartment

III. Mechanical Inspection

- ☐ Keyboard
- ☐ Battery Door
- ☐ Cassette Latch
- ☐ Cassette Lock

IV. Functional Inspection

- ☐ Power-up
- ☐ Latch / Lock
- ☐ Cassette Sensor
- ☐ LCD
- ☐ Motor / Gear Train
- ☐ RES VOL Alarm
- ☐ Stop / Start
- ☐ Activation Timing
- ☐ Remote Dose Cord
- ☐ Dose Given / Attempted
- ☐ MG Given
- ☐ Air Detector
- ☐ Printer Tests

V. Occlusion Tests (Only need to perform 1 or 2; not both)

Downstream Option 1: Activations Before Alarm _____

Downstream Option 2: High Pressure Alarm At _____ psi

Upstream Occlusion Sensor Test

Pass _____ Fail _____

VI. Accuracy Testing (Only need to perform 1 or 2; not both)

Volumetric Accuaracy Test

Intended Delivery Volume	Actual Delivery Volume	Inaccuracy Volume	Accuracy Error	Accuracy Error Percentage
ml	ml	ml		%

Gravimetric Accuracy Test

Pre-Delivery Weights	Post-Delivery Weight	Amount Delivered	Intended Delivery Volume	Inaccuracy Volume	Accuracy Error	Accuracy Error
g	g	ml	ml	ml		%

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The products described are covered by one or more of the following U.S. Patent Nos., 4,559,038; 4,565,542; 4,650,469; 5,181,910; 5,338,157; 5,364,242; 5,485,408; 5,531,697; 5,531,698; 5,538,399; 5,540,561; 5,564,915; 5,567,136; 5,567,119; 5,695,473 (Model 6101 only); other patent(s) pending.

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